Section 1: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. General Information

Device Name

Trade Name:	13C/1H occipital headcoil for MAGNETOM Allegra
Classification Name:	Magnetic Resonance Diagnostic Device
CFR Section:	CFR § 892.1000
Classification:	Class II
Product Code:	MOS - Magnetic Resonance Specialty Coil

Manufacturer

Bruker BioSpin MRI GmbH
Rudolf-Plank-Straße 23
D-76275 Ettlingen, Germany

Registration Number 9612385

Initial Importer/ Distributor

Siemens Medical Solutions, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Registration Number 2240869

Contact Person

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Performance Standards

None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Supporting Substantial Equivalence

Device Description
The 13C/1H occipital headcoil for MAGNETOM Allegra is a transmit/receive surface coil type 1H-quadrature/13C linear headcoil double resonant on carbon (13C) and proton (1H) frequencies. It is optimized for the main application: 13C spectroscopy potentially including proton decoupling.

The coil consists of the resonator and an electronic box which serves for switching transmit/receive, quadrature splitting, preamplifying and lowpass filtering in the receive pathway. The latter being essential for proton decoupling.

Intended Use
The 13C/1H occipital headcoil for MAGNETOM Allegra is a transmit/receive surface coil type headcoil double resonant on carbon (13C) and proton (1H) frequencies.

Used in the Allegra system it is indicated for use as a diagnostic imaging device to produce 1H images and 1H spectra of the internal structures of the head. In addition, 13C spectra can be obtained within the same session without changing the coil.

The images produced reflect the spatial distribution of protons exhibiting magnetic resonance. Spectra allow the molecules in which the nucleus under investigation is contained to be distinguished. The NMR properties that determine the image and spectra appearance are spin density, spin-lattice relaxation time (T1), spin-spin echo time (T2) and resonance frequency of the corresponding nucleus.

When interpreted by a trained physician, these images and spectra provide information that can be useful in determining diagnosis.

Substantial Equivalence
Bruker and Siemens believe that, within the meaning of the Safe Medical Devices Act of 1990, the 13C/1H occipital headcoil for MAGNETOM Allegra is substantially equivalent to three coils:

Coil Name	Premaket Notification	Clearance Date
Siemens Medical Solutions 31P/1H heart/liver coil for Clinical Phosphorus Spectroscopy Option MAGNETOM Vision	K962627	March 04, 1997
Siemens Medical Solutions 31P/1H heart/liver coil included in *syngo* MR 2002B	K020991	June 13, 2002
GE Medical Systems Signa 1.5T Phosphorus Transmit/Receive Flex Coil	K983139	February 19, 1999

Although these coils are designed for non-invasive in vivo detection of phosphorus-31-metabolites instead of the carbon-13-metabolites detectable with the coil described in this submission, we believe that they are substantially equivalent Magnetic Resonance Specialty Coils for spectroscopy of nuclei other than protons (1H), the latter being used for magnetic resonance imaging (MRI).

There are numerous publications by researchers worldwide to support the usefulness of 13C spectroscopy. No risks different to standard MRI occur for the patient during these investigations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Ms. Nealie Hartman
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Re: K042718
Trade/Device Name: 13C/1H occipital headcoil for MAGNETOM Allegra System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: September 29, 2004
Received: September 30, 2004

Dear Ms. Hartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.